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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/284,327 | 04/10/1999 | Benjamin S. Bower | GC516-2-US | 2162 |

5100 7590 12/05/2005

GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
925 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER

PATTERSON, CHARLES L JR

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1652

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/284,327

Applicant(s)

BOWER ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 1999 and 04 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-12 and 25-30 not directed to Asn-Asn-(Leu/Phe/Lys/Ile)-Trp-Gly are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicants have cancelled claims 12-24 but have not cancelled the parts of claims 1-12 and 25-30 that are not directed to Asn-Asn-(Leu/Phe/Lys/Ile)-Trp-Gly. Thus parts "(b)" through "(e)" of claim 1 and dependent claims will not be examined. This was noted in the action mailed 8/26/03 but applicants did not respond to it in the amendment filed 4/4/05.

Claims 1 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing in the recitation of "An EGI-III-like enzyme comprising cellulolytic activity..." An enzyme does not "comprise" activity but rather has activity. It comprises some amino acid sequence.

Claim 27 is confusing and indefinite in the recitation of "to claim." There is no claim indicated and therefore this claim will not be further examined at this time.

Applicants' reply in the instant amendment that they disagree with the examiner's previous assertion that claim 4 does not further limit claim 1 is noted. That is not what was stated in the previous action but rather that "claim 4 does not further limit claim 2 to a fungus but merely further defines the fungus". That characterization is maintained. Claim 4 limits claim 1 to a filamentous fungus, a bacteria and an Actinomycete.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following 35 USC § 112 first paragraph rejection is split into a written description and an enablement rejection. Since the previous action was written on 8/26/03 it has been decided that there should properly be two rejections, not a combination rejection as in the previous action. Separating the two rejections does not change what was rejected previously in the combination rejection.

Claims 1-12 and 25-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants argue that the specification teaches how to identify and produce cellulases and that "the amino acid sequence (base structure) and function (cellulolytic activity) are well described throughout the Specification". For an application to provide adequate written description of a protein, the inventor must be able to envision the detailed structure of the protein, i.e. have the protein in hand. A mere method of making the protein along with its biological activity is simply a wish to know the identity of any material with that activity, not a proper written description of the protein. The specification does not teach that applicants had in their posses-

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sion or were able to envision all of the proteins having the partial sequence of Asn-Asn-(Leu/Phe/Lys/Ile)-Trp-Gly that are "EGIII-like comprising cellulolytic activity". It certainly does not teach that applicants had in their possession any and all unknown derivatives of the enzymes, which could entail any number of changes not defined. None of the sequences shown in Figs. 3 or 6 have been shown to have "cellulolytic activity", as required by the instant claims. Therefore it is maintained that applicants did not possess the instant application at the time the application was filed.

Claims 1-12 and 25-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants argue that only "objective enablement...either by the use of illustrative examples or by broad terminology...[is required and that] a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein", citing *In re Marzocchi*. The instant claims are drawn to "An EGIII-like enzyme comprising...[the indicated partial amino acid sequence] or a derivative of said enzyme" that is greater than 30% identical with EGIII from organisms other than *Trichoderma* spp. The only

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thing taught by the specification is that certain primers coding for certain amino acid sequences, including the primer for the elected sequence, were used in a PCR reaction. The partial sequences between 250-500 base pairs were isolated (Fig 3) and sequenced and the full length genes were then determined. There is absolutely no teaching in the specification that any of these sequences have cellulolytic activity, as required by the instant claims, nor certainly not the that "a derivative of said enzyme" has enzymatic activity. It is maintained that undue experimentation would have been required for one of ordinary skill in the art to produce any and all protein sequences having the elected partial sequence and to determine if this is an "EGIII-like enzyme comprising cellulolytic activity" given the teachings of the instant specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitamoto, et al. (BB) or Ooi, et al. (BE). This rejection is re-

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peated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants state that they "have amended Claim 1 to recite at least 60% identity with EGIIII". The copy of claim 1 filed with this amendment states that "said enzyme has an amino acid sequence identity with...(SEQ ID NO:8) of greater than 30%", not 60%. The examiners search determined that Kitamoto, et al. is 47.3% identical and Ooi, et al. is 55.6% identical.

Claims 1-9, 11 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitamoto, et al. (BB) or Ooi, et al. (BE) in view of Ward, et al. (AG) or Fowler, et al. (A) and the admitted prior art. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

As stated *supra*, the primary references teach claims 1-9 and 11. Applicants state that "neither Ward nor Fowler provide an enzyme from an organism other than *Trichoderma* [and] [c]ombining them with any other reference fails to give the currently claimed invention". This characterization is not agreed with. To start with the rejection was made over Kitamoto, et al. and Ooi, et al. in view of Ward, et al. or Fowler, et al. "and the admitted prior art". Therefore Ward and Fowler are not needed in the rejection. Secondly, the fact that "neither Ward nor Fowler provide an enzyme from an organism other than *Trichoderma*" does not preclude them from being used as secondary references to teach the uses in claims 25-30.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

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See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the

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Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "C. Patterson".

Charles L. Patterson, Jr.
Primary Examiner
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Patterson
November 29, 2005